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T.B.

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/401,632

09/22/99

SCHLESINGER

R

5050/582

EXAMINER

QM32/0509

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ART UNIT	PAPER NUMBER
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3763

DATE MAILED:

05/09/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/401,632

Applicant(s)

SCHLESINGER ET AL.

Examiner

Catherine Serke

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 48 is/are allowed.
- 6) ☐ Claim(s) 1-24 and 26-46 is/are rejected.
- 7) ☐ Claim(s) 25 and 47 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

*Cancelled
these* Claims 10, 12-14, 38 and 42-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Hamm et al.

Hamm discloses an ultrasound imaging guidewire which during use is part of a catheter system. The device includes conductor 103, shaft 29, non-conductive braid 110 (knitted layer of Kevlar, see 15: 16+), ultrasound transducer assembly 23, dielectric film (silicone oil) 12, window 31, and floppy tip 26. It is considered inherent that the device has a control for the braid 110 in light of the fact that the device has torqueability and pushability from the proximal region. As shown in figure 2, the conductor 103 is connected with transducer 22 within the shaft.

In regard to claims 10 and 12-14, the non-conductive braid 110 may be embedded within the outer tubular member 29. The specification states that the reinforced coil layer 110 (interchangeable with the Kevlar layer) may be disposed within and bonded to the outer tubular member (see 7:49-52).

In regard to claims 38 and 42-43, silicone oil has a high dielectric strength and is used extensively as an insulator. The use of silicone oil in Hamm reads on “a dielectric film” since

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the silicone oil will be compressed into a fluid film layer when disposed in the annular gap between solid couplant 11 and the layer of knitted Kevlar 110 and in the space 12 at the distal end of the transducer. Looking at figure 2, the silicone oil is dispersed in the annular gap, which extends above and below the transducer.

Maintain req.
Claims 15-19, 21-22, 24, 26, 38-40 and 43-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Eberle.

Eberle discloses a high resolution intravascular ultrasound transducer assembly having a flexible substrate that includes a shaft (considered inherent), an ultrasound transducer (see figures 3-4), lens or window (considered inherent), and a Kapton film/tape or alternatively Mylar (polyester film) that makes up the dielectric film. The dielectric film surrounds a circumference of the transducer and a portion of both ends and once placed inside a catheter shaft the dielectric film would be positioned between the transducer and catheter shaft, see figure 5. It is considered inherent that the catheter shaft will have a tip portion. Finally, regardless of where the transducer is placed within the catheter shaft that location will be connected, albeit possibly indirectly, with the tip portion.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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*Cancelled
Here*

Claims 11 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamm et al.

Hamm meets the claim limitations as described above but fails to include a braid of monofilament material and the non-conductive insert comprising LCP.

At the time of the invention, it would have been obvious to substitute layer 110 of Hamm with a monofilament braid or liquid crystal polymer in view of the fact that these are well known catheter shaft materials and it has been held to be within the general skill of a worker in the art to select a known material based on its suitability for the intended use. (See response to Arguments below)

Claims 1, 4-9, 29, 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamm et al in view of Crowley et al.

Hamm meets the claim limitations as described above but fails to include the ultrasound transducer positioned in a tip portion of the shaft. However, Crowley (parent patent to Hamm et al) discloses an acoustic imaging catheter that positions the transducer in the tip of the catheter.

At the time of the invention, it would have been obvious to re-position the transducer in the catheter by Hamm to the tip of the catheter as taught by Crowley, since Hamm is a continuation in part of Crowley. Catheters with ultrasound transducers at the tip, as taught by Crowley, are well known in the art and the motivation would have been to combine the improved maneuverability and torqueability of Hamm with a standard tip ultrasound catheter design.

Claims 2-3, 30-31 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hamm et al in view of Crowley et al.

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Hamm in view of Crowley meet the claim limitations as described above but fail to include the non-conductive braid being made from a monofilament, a monofilament nylon, or a monofilament liquid crystal polymer material.

At the time of the invention, it would have been obvious to substitute the braid of Hamm in view of Crowley with a monofilament, a monofilament nylon, or a monofilament liquid crystal polymer material in view of the fact that these are well known catheter shaft reinforcement materials and it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. (See response to Arguments below)

Claims 20, 27 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eberle et al.

Eberle meets the claim limitations as described above but fails to include the dielectric film having a thickness of less than 7 microns.

At the time of the invention, it would have been obvious to make the dielectric film of Eberle having a thickness of less than 7 microns since the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

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Claims 23, 28 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eberle et al in view of Zdrahala or Mahurkar et al.

Eberle meets the claim limitations as described above but fails to include a non-conductive braid within the catheter shaft. However, Zdrahala or Mahurkar et al discloses using LCP or nylon, respectively, to reinforce the catheter shaft.

At the time of the invention, it would have been obvious to incorporate the reinforced shaft of either Zdrahala or Mahurkar et al into the invention of Eberle since (1) incorporating reinforcing structures into catheter shafts is well known in the art and (2) the motivation would be in order to improve the pushability and torqueability of the catheter.

Allowable Subject Matter

Claim 48 is allowed.

Claims 25 and 47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 2/22/01 have been fully considered but they are not persuasive.

In regard to claims 2-3, 11, 30-31 and 36-37 and applicant's argument that the examiner does not provide a basis for nylon and liquid crystal polymer being known catheter shaft materials, the examiner draws attention to two U.S. patents (5,248,305 and 5,221,255). These

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references, among others in class 604 subclass 526 (lumen enforced by embedded or coiling strands) teach using nylon and liquid crystal polymer for reinforcing a catheter shaft. The concept of using polymer strands/fibers, including nylon and LCP, for catheter shaft reinforcement is well known in the art and by one skilled in the art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine Serke whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharon Kennedy can be reached on 703-305-0154. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.



Catherine Serke
May 6, 2001


Sharon Kennedy
Primary Examiner